

**Remarks**

Claims 1-15 are pending in the application. Applicants thank the Examiner for reconsideration of the Restriction Requirement, and the rejoinder of claim 13-15.

Claims 1 and 12 have been amended. Support for the amendment can be found throughout the specification including, for example, paragraphs [0013] – [0014]. No new matter has been added.

**Rejection under 35 U.S.C. § 102**

Claims 1, 2, 4, 6-7 and 11-15 stand rejected under 35 U.S.C. § 102(b) as anticipated by Plattner, *et al.* (U.S. Patent No. 4,219,497). Applicants respectfully disagree with the rejection, and ask that the rejection be withdrawn for the following reasons.

Plattner, *et al.* does not anticipate the claimed invention because Plattner, *et al.* does not teach each and every element of independent claims 1, 12 and 13. In particular, with regard to claims 1 and 12, Plattner, *et al.* does not teach the method of determining AT in a single reaction mixture as presently claimed. In Plattner, *et al.*, two separate assays are described. First, total anti-thrombin activity is determined by the addition of heparin. (*See* Plattner, *et al.*, col. 6, lns. 38-48). In this step, thrombin becomes associated both with AT-III and with interfering substances (*e.g.* drugs) that may be present in the sample. Excess thrombin is then determined. Then, in a second assay, anti-thrombin activity is measured in the absence of heparin. (*Id.* col., 6., lns. 52-55). In this step, only the interfering factors are expected to associate with thrombin. The results of these two assays can be compared and AT-III can be determined.

The two assays of Plattner, *et al.* are different than the method of claim 1, which provides for a method of detecting AT-III in samples that may contain interfering factors in a single

reaction mixture. Also, contrary to the first step of Plattner, the claimed method does not determine total anti-thrombin activity. Instead, in the claimed method, anti-thrombin activity not associated with AT-III (steps a and b) is first determined. Then, *in the same reaction mixture*, the quantitative determination of the AT activity based upon AT-III is determined (step c).

Accordingly, Plattner, *et al.* does not teach each and every element of claim 1 and dependent claims 2, 4, 6-7 and 11-12. Therefore, Applicants request that the rejection of claims 1, 2, 4, 6-7 and 11-12 over Plattner, *et al.* be withdrawn.

With regard to claim 13, Plattner, *et al.* does not teach a kit for determining AT-III as presently claimed. In particular, Plattner, *et al.* does not address the components of a kit, and does not teach a kit that would include both, as separate components, (a) a first reagent R1 containing an AT binding partner, and (c) a third reagent R3 that contains an accelerator. Accordingly, Plattner, *et al.* does not teach each and every element of claim 13, and dependent claims 14 and 15. Therefore, Applicants request that the rejection of claims 13-15 over Plattner, *et al.* be withdrawn.

### **Rejections Under 35 U.S.C. § 103**

Claims 8-9 stand rejected as obvious under 35 U.S.C. § 103(a) over Plattner, *et al.* in view of Exner (U.S. 6,051,434). Applicants respectfully disagree with the rejection because the combination of Plattner, *et al.* and Exner does not teach each and every element of independent claim 1. Exner is cited as teaching the use of polybrene in reagent R1. However, Exner does not address the missing elements of claim 1 in Plattner, *et al.* as noted above. Accordingly, the combination of Plattner, *et al.* and Exner can not render obvious claims 8 and 9, which depend

from claim 1. Therefore, Applicants request that the rejection of claims 8-9 under 35 U.S.C. § 103 be withdrawn.

Claim 10 stands rejected as obvious under 35 U.S.C. § 103(a) over Plattner, *et al.* in view of Nesheim, *et al.* (U.S. 4,219,497). Applicants respectfully disagree with the rejection because the combination of Plattner, *et al.* and Nesheim, *et al.* does not teach each and every element of independent claim 1. Nesheim, *et al.* is cited as teaching the use of purified Factor XA in order to perform a competition assay with heparin for AT III activity to determine the level of heparin activity. However, Nesheim, *et al.* does not address the missing element of claim 1 in Plattner, *et al.* as noted above. Accordingly, the combination of Plattner, *et al.* and Nesheim, *et al.* can not render obvious claim 10, which depends from claim 1. Therefore, Applicants request that the rejection of claim 10 under 35 U.S.C. § 103 be withdrawn.

### **Conclusion**

There may be other reasons for patentability for independent and dependent claims, and Applicants do not waive those arguments by failing to assert those arguments here. Applicants view the foregoing reasons as sufficient to establish that the claims are nonobvious, but Applicants expressly reserve the right to make further argument regarding patentability of the claims in future proceedings.

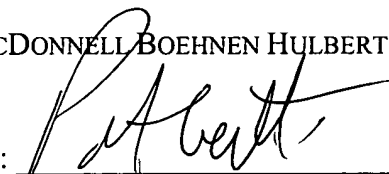
With the above Amendments and Remarks, the Applicants respectfully submit that the application is now in a condition for allowance. If the Examiner is of the opinion that a

telephone conference would expedite prosecution of the application, the Examiner is encouraged to contact Applicants' undersigned representative.

Respectfully submitted,

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